

REMARKS

In the Office Action of May 9, 2003, the Examiner objected to the abstract, objected to claims 41 and 51 for informalities and objected to the use of the term nitinol in the specification. Each of the objections should be withdrawn for the reasons explained below.

Applicants file herewith an abstract on a separate sheet to replace the originally-filed abstract. This replacement abstract complies with M.P.E.P. § 608.01(b). Accordingly, Applicants respectfully request the withdrawal of the objection to the Abstract.

Applicants also have amended claims 41 and 51 to recite --xenograft-- instead of "zenograft." The amendments to claims 41 and 51 are solely to correct a typographical error and do not affect the scope of the claims, as Applicants originally intended for the term "xenograft" to appear in the claims. Accordingly, Applicants respectfully request the withdrawal of the objection to claims 41 and 51.

The Examiner objected to the use of the term nitinol in the specification, alleging that the term is a trademark. Nitinol is an acronym for nickel titanium naval ordnance laboratory, see, e.g., Merriam-Webster's Collegiate Dictionary 784 (10th ed. 2001), and is currently not a registered trademark. Under the provisions of M.P.E.P. 608.01(v), Applicants believe that the term nitinol, as used in this application, does not meet the definition of a "trademark" but instead meets the definition of a "name used in trade." Accordingly, because Applicants believe that their use of the term nitinol in the specification is proper under the provisions of M.P.E.P. 608.01(v), Applicants respectfully request withdrawal of that objection.

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In the Office Action, the Examiner rejected claims 35-39, 42-49, 52, and 53 under 35 U.S.C. § 102(b) as being anticipated by Wilk (U.S. Patent No. 5,429,144), rejected claims 41 and 51 under 35 U.S.C. § 103(a) as being unpatentable over Wilk in view of Porier et al. ("Porier") (U.S. Patent No. 4,118,806); and rejected claims 40 and 50 under 35 U.S.C. § 103(a) as being unpatentable over Wilk in view of Davies et al. ("Davies") (U.S. Patent No. 6,197,296).

Of the claims rejected based on Wilk, claims 35 and 44 are independent. Claim 35 recites, among other things, "providing a conduit with a first end and a second end" and "providing a natural valve." Claim 44 recites, among other things, "a tube having a first end and a second end. . . and a natural valve." Wilk fails to disclose or otherwise suggest the claimed invention.

At page 3 of the Office Action, the Examiner asserts that "Wilk discloses a conduit or stent having a first and second end for placement in the heart wall for creating a passage between the left ventricle and a coronary artery (see figure 2A). The stent has an inner layer that is a vascular graft including a natural valve that is taken from the individual prior to the bypass method."

Referring to column 8, lines 47-58, and to Figs. 8A, 8B, and 9, Wilk discloses a stent 78 for use in a bypass procedure. In the embodiment shown, stent 78 is provided with an inner layer 82 formed from a vascular graft. Wilk further discloses that when stent 78 includes a valve, such as the valve 68 shown in Figs. 7A and 7B, "two vascular graft sections [should be inserted] into the prosthetic device from opposite ends thereof." (Col. 8, lines 55-58).

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However, contrary to the Examiner's assertion, Wilk does not disclose that the vascular graft sections which are used in combination with the stent 78 include a natural valve. Rather, Wilk teaches providing a manufactured mechanical valve in a stent with two separate vein grafts lining the stent on opposite sides of the valve. Accordingly, Wilk does not disclose or otherwise suggest, and indeed teaches away from, "providing a natural valve," as recited in claim 35 or "a natural valve," as recited in claim 44. Applicants therefore respectfully request the withdrawal of the section 102(b) rejection of claims 35 and 44 and their respective dependent claims 36-39, 42-43 and 45-49, 52 and 53, based on Wilk.

Regarding the Examiner's rejection of claims 41 and 51 under 35 U.S.C. § 103(a) as being unpatentable over Wilk in view of Porier and rejection of claims 40 and 50 under 35 U.S.C. § 103(a) as being unpatentable over Wilk in view of Davies, Applicants traverse this rejection for the reasons set forth below.

Applicants respectfully note that "the examiner bears the initial burden, on review of the prior art on any other ground, of presenting a *prima facie* case of unpatentability." In re Oetiker, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992) (Emphasis original). To establish a *prima facie* case of unpatentability, the cited references must teach or suggest all of the limitations. M.P.E.P. §2143.

As set forth above, Wilk neither discloses nor suggests all of the limitations of claims 35 and 44, from which claims 40, 41, 50, and 51 respectively depend. For example, instead of teaching a natural valve, Wilk teaches the use of a manufactured mechanical valve 68. Porier discloses a method of forming tissue equivalents. Davies discloses a rigid implantable prosthetic blood vessel. Porier and Davies do not remedy

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the aforementioned deficiencies of Wilk, and skilled artisans would not be motivated to modify Wilk with the respective teachings of Porier and Davies. Indeed, the Examiner has not asserted otherwise in the Office Action. Accordingly, Applicants respectfully request the withdrawal of the 103(a) rejections of dependent claims 40, 41, 50, and 51, based on Wilk in view of either Porier or Davies.

Claims 35-38 and 42-53¹ were rejected under an obviousness-type double patenting in view of claims 1-7, 11, 12, 13, 18, 19, 24, 25, 28 and 30 of U.S. Patent No. 6,254,564 ("564 patent").

In the obviousness-type double patenting, the Examiner asserts that "both the application claims and the patent claim recite a method for allowing blood to flow or shunt from the left ventricle to the coronary artery via a conduit having a natural valve with the lumen." The Examiner further asserts that "both the application claims and the patent claim recite a bypass system or conduit for allowing blood to flow or shunt from the left ventricle to the coronary artery via conduit having a natural valve within the lumen." Applicants disagree with the Examiner's characterizations and assertions regarding the application claims and the patent claims. For example, Applicants disagree with the Examiner's assertion that both the application claims and the patent claims recite "allowing blood to flow or shunt from the left ventricle to the coronary artery via a conduit having a natural valve within the lumen."

Nonetheless, in the interests of expediting the prosecution of this application, Applicants submit herewith a Terminal Disclaimer in compliance with 37 C.F.R.

¹ At page 6 of the Office Action, the Examiner rejects claim 54 under the obviousness-type double patenting rejection. Applicants assume that this is a typographical error as claim 53 is the highest numbered pending claim.

§ 1.321(c). The filing of the Terminal Disclaimer in no way manifests an admission by Applicants as to the propriety of the double patenting rejection or an acquiescence to the assertions and characterizations set forth therein. See M.P.E.P. § 804.02, citing Quad Environmental Technologies Corp. v. Union Sanitary District, 946 F.2d 970, 20 U.S.P.Q.2d 1392 (Fed. Cir. 1991). (“In legal principle, the filing of a terminal disclaimer simply serves the statutory function of removing the rejection.”) Should the need arise at a later date, Applicants reserve the right to present arguments regarding the merits of the double patenting rejections set forth in the Office Action and the nonobviousness of application claims 35-38 and 42-53 in view of ‘564 patent claims 1-7, 11, 12, 13, 18, 19, 24, 25, 28, and 30.

As discussed above, dependent claims 36-43 and 45-53 depend either directly or indirectly from one of claims 35 and 44, respectively, and thus are allowable for the same reasons those claims are allowable. In addition, at least some of the dependent claims recite unique combinations that are neither taught nor suggested by the art and therefore also are separately patentable.

Applicants respectfully request the withdrawal of the outstanding objections and rejections, and the timely allowance of the claims 35-53.

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

In discussing the specification, claims, abstract, and drawings in this Amendment, it is to be understood that Applicants are in no way intending to limit the scope of the claims to any exemplary embodiments described in the specification or

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abstract and/or shown in the drawings. Rather, Applicants believe that they are entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: July 31, 2003

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